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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE J. 0221-00036 09/760,897 01/17/01 HARRINGTON **EXAMINER** HM12/0625 FORMAN, B SHANKS & HERBERT PAPER NUMBER ART UNIT TRANSPOTOMAC PLAZA 1033 N. FAIRFAX ST., SUITE 306 1655 ALEXANDRIA VA 22314 DATE MAILED: 06/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

PTO-90C (Rev.11/00) 1- File Copy

	Application No.	Applicant(s)
Office Action Summary	09/760,897	HARRINGTON ET AL.
		Art Unit
	Examiner	
	BJ Forman	1655
The MAILING DATE of this communication appears on the cover sheet with the correspondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status		
1) Responsive to communication(s) filed on		
24)	This action is non-final.	matters, prosecution as to the merits is
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 30 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>30</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claims are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are objected to by the Examiner.		
11) The proposed drawing correction filed on is: a) approved b) disapproved.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) All b) Some * c) None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
* See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).		
Attachment(s)		
<ul> <li>15) Notice of References Cited (PTO-892)</li> <li>16) Notice of Draftsperson's Patent Drawing Review (PTO-97)</li> <li>17) Information Disclosure Statement(s) (PTO-1449) Paper</li> </ul>	948) 19) 🔲 No	erview Summary (PTO-413) Paper No(s) tice of Informal Patent Application (PTO-152) er:

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#### **DETAILED ACTION**

### Specification

1. The abstract of the disclosure is objected to because it consists of over 150 words. A new abstract of 150 or fewer words on a separate sheet is required. See MPEP § 608.01(b).

## Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 30 is indefinite in the preamble for the recitation "primer molecule comprising.....a degenerate 3' terminus", because it is unclear whether "TTTATT-3'" is the degenerate 3' terminus or whether there is a degenerate terminus 3' to the structure illustrated in the claim. It is suggested that the claim be amended to clarify e.g. at the end of the claim insert "wherein the degenerate terminus consists of "TTTATT-3'".

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The claim is drawn to a molecule <u>comprising</u> a PCR-amplifiable sequence and a degenerate 3' terminus, wherein said molecule <u>has</u> the structure: 5'-(dT)<sub>a</sub> -X-N<sub>b</sub>-TTTATT-3' wherein a is a whole number from 1 to 100, X is a PCR-amplifiable sequence consisting of a nucleic acid sequence of about 10-20 nucleotides in length, N is any nucleotide and b is a whole number from 0 to 6 and wherein the intended use is as a primer. The claims are given the broadest reasonable interpretation consistent with the open claim language "comprising" and "has".

5. Claim 30 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Davies et al. (Genomics 1994, 24(3): 456-463).

Regarding Claim 30, Davies et al. disclose the claimed structure wherein a is 14, X is a PCR-amplifiable sequence consisting of a nucleotide sequence of 18 nucleotides in length, N is the nucleotide C, and b is 1 i.e. GenBank Acc. No. Z36503.

6. Claim 30 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bouma et al. (U.S. Patent No. 5,484,699, issued 16 January 1996).

Regarding Claim 30, Bouma et al. disclose the claimed primer molecule comprising a PCR amplifiable sequence and a degenerate terminus, wherein a is 5, X is a PCR-amplifiable sequence consisting of a nucleotide sequence of 12 nucleotides in length, N is the nucleotide G, and b is 1 i.e. SEQ ID NO: 31, PCR13 (Example 4, SET4, Column 10, line 26-Column 11, first table, and Table 5 top of Columns 13-14).

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7. Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by Hama et al. (U.S. Patent No. 5,919,654, filed 1 February 1996).

Regarding Claim 30, Hama et al. disclose the claimed primer molecule comprising a PCR amplifiable sequence and a degenerate terminus, wherein a is 1, X is a PCR-amplifiable sequence consisting of a nucleotide sequence of 20 nucleotides in length, N is the nucleotide T, and b is 1 i.e. SEQ ID NO: 28, Example 16, Column 16, lines 36-67).

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D. June 22, 2001 This was the Manual of the Control o